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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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21 CFR Part 556

Tolerances for Residues of New Animal Drugs in Food; Moxidectin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is updating the animal drug regulations to correctly reflect the tolerance for moxidectin in cow's milk. This document amends the regulations to state the correct tolerance is 40 parts per billion (ppb). This action is being taken to improve the accuracy of the agency's regulations. Changes to a current format are also being made.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578.

SUPPLEMENTARY INFORMATION: Moxidectin solution is approved for topical use in cattle for the treatment and control of infections and infestations of certain internal and external parasites. When the November 2, 1999, approval of the use of moxidectin in lactating dairy cows was published in the **Federal Register** of June 9, 2000 (65 FR 36616), the tolerance for parent moxidectin in the milk of cattle was incorrectly listed. At this time, the regulations are being amended in 21 CFR 556.426 to state the correct tolerance is 40 ppb and, editorially, to reflect current format.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

NFR 1

List of Subjects in 21 CFR Part 556

Animal drugs, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 556 is amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

2. Section 556.426 is amended by revising paragraph (b) to read as follows:

§ 556.426 Moxidectin.

* * * * *

(b) *Tolerances*—(1) *Cattle*—(i) *Liver (the target tissue)*. The tolerance for parent moxidectin (the marker residue) is 200 parts per billion (ppb).

(ii) *Muscle*. The tolerance for parent moxidectin (the marker residue) is 50 ppb.

(iii) *Milk*. The tolerance for parent moxidectin (the marker residue in cattle milk) is 40 ppb.

(2) [Reserved]

Dated: 11/29/00

November 29, 2000.

David R. Newkirk,
Acting Deputy Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

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